



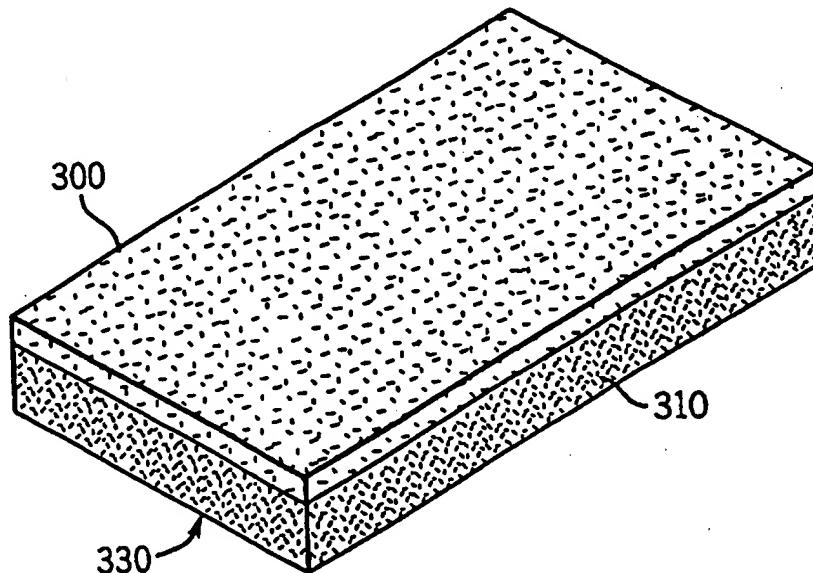
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: <b>PCT/US99/31040</b></p> <p>(22) International Filing Date: <b>29 December 1999 (29.12.99)</b></p> <p>(30) Priority Data: 09/222,111                      29 December 1998 (29.12.98)      US</p> <p>(71)(72) Applicant and Inventor: <b>MCADAMS, John, Brian</b> [US/US]; 1319 East Hillsboro Boulevard, Deerfield Beach, FL 33441 (US).</p> <p>(74) Agent: <b>SCHMIDT, Richard, D.; Venable, P.O. Box 34385,</b> Washington, DC 20043-9998 (US).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report.</i></p>

(54) Title: A METHOD AND ARTICLE FOR DEBRIDEMENT AND DETOXIFICATION OF WOUNDS

## (57) Abstract

A method for delivering a sub-epidermal treatment by preparing a medicating solution and saturating a saturatable material with sufficient abrasive characteristics to abrade the epidermis and abrading said epidermis where a said abrasion enables sub-epidermal delivery of said medicating solution in said saturated material.



## A Method and Article for Debridement and Detoxification of Wounds

### Technical Field

The invention relates to a method to treat bites, stings or wounds caused by fire ants, sea lice, related arthropod and *Cnidarians*, as well as other biological wounds and envenomations.

### Background of the Invention

5        Fire Ants (*Solenopsis*), sea lice (one of 1000 species of *Cnidarians*), and related arthropod and *Cnidarians* have in many ways made tropical paradises the bane of many human visitors from colder climates. Of particular concern is the fire ant or *Solenopsis Invicta* or *S. Invicta* that was inadvertently introduced to the United States by a freighter in Texas that had arrived from South America. There were some species of *Solenopsis*  
10        indigenous to the United States prior to the arrival of *Solenopsis Invicta*. The arrival of *S. Invicta* or fire ants has caused great concern because the fire ants' aggressive behavior, expanding migration throughout the North American, ruggedness, and especially because of the highly painful, toxic and morbid stings of these little creatures. Not only is the sting of the *S. Invicta* highly painfully, in some cases it has been fatal to the recipient. Since *S.*  
15        *Invicta* forages in packs, seldom does a victim receive just a single sting. *S. Invicta* release an airborne chemical that acts as a message that one is in the attack mode and this triggers all nearby *S. Invicta* to begin the attack on the same prey. The debilitating effect of such massive attacks, and overwhelming lighting assault oftentimes causes smaller creatures to become incapacitated, leaving them as easy prey for the entire nest of *S. Invicta*.

20        Although introduced in Texas 50 years ago, *S. Invicta* or the fire ant, now ranges from Virginia to California and most states of the Union and Countries of the World south of that latitude. Humans are not the only victims of *S. Invicta*, but all creatures have been known to fall prey. Juveniles and particularly newborns are especially vulnerable to *Solenopsis Invicta*. In Florida, one of the numerous dangers for sea turtles is *S. Invicta*  
25        because they attack the turtle's nest, eggs and newly hatched young with zeal.

Despite the horrendously painful sting, which endures for hours, what is even worse in the pustule formation. The pustule, which resembles a small boil or a large white head pimple, invites rupture either intentionally or accidentally because of its raised distended presence. Once rupture, those open sores are susceptible to infection particularly

because they are usually rubbed or scratched by the recipient who is irritated by these repulsive pustules and subsequent sores. The infection of these sores almost always results in some form of scarring to the recipient.

Problems with all *Cnidarians* sea lice (incorrectly called that by the public and the named has stuck) or the larval stage of the thimble jellyfish (*Linuche Unquiculata*) are as acute, but the fire ant envenomation occurs more often probably because both fire ant and the human are land based creatures.

The treatment of the current invention is directed in this instance to deal with fire ant, sea lice and related arthropod and *Cnidarians*, as well as all other similar biological intoxications. Current treatments for envenomation by fire ants and *Cnidarians* are similar and done as much for the placebo effect as for true efficacy, especially topical treatments. Often the treatments of choice are topical measures such as the application of a cortisone cream, colloidal preparation, or the omnipresent calamine solution. In more severe cases, antihistamines, steroids, and epinephrine may be administered by I.M., I.V., and/or orally. In all cases the recipient is told not to scratch or abrade the wound in any way.

#### Summary of the Invention

There are a few instances noted in the literature of home remedies, and several noted in Dangerous Marine Animals, by Dr. Bruce W. Walstead of the World Life Research Institute that are of interest. Halstead on several occasions refers to using sand or adhesive tape to strip the wound site after a sting. Auerbach recommends the use of shaving cream and a balded razor to strip the outer layers for treatment of biological envenomations. Such an act seems to be clearly counter to the accepted practice for treating such stings.

The basis for the current invention to treat such stings is founded on the concept of preparation of the wound site and delivery fo the toxin antagonist. A generally inert material in the form of a pad with an abrasive texture is saturated with a solution specific to the desired action in various instances. The texture of the pad can be seen as being similar to the surface of pads used in the kitchen for cleaning pots and pans. The wound or sting is scrubbed with the pad containing the solution. The key is the application of the solution during the abrading or scrubbing of the wound. The solution that saturates the pad can be a ratio of soap and water that provides sufficient detergence to clean the wound and a pH desired lavage. Furthermore, the pads can be impregnated with various solutions

composed of enzymes, hypo-allergenic soap solutions, antihistamines solutions, anesthetic solutions, antibacterial solutions, antifungal solutions, antibiotic solutions, and combinations of any of the above for the specific treatment desired.

#### Brief Description of the Drawings

- 5           Figure 1 illustrates the length of typical *Solenopsis Invicta* stinger.  
            Figure 2 illustrates the average human epidermal layer of skin.  
            Figure 3 illustrates an armed nematocyst.  
            Figure 4 illustrates a discharged nematocyst.  
            Figure 5 illustrates a side projected view of a pad containing a typical solution.

#### 10   Preferred Embodiments of the Invention

*Solenopsis Invicta* is a specific group of ants that are internationally known for their aggressive behavior and their extremely painful and dangerous stings. Some of the stings of the *Solenopsis Invicta* have been fatal. Characteristic of *Solenopsis Invicta* and a host of other stinging arthropod is that their toxins although powerful are largely deposited  
15   in rather shallow wound sites due to the diminutive size of the stinger. As illustrated in Figure 1, the Stinger 10 has a length of about 100 microns. The glandular epithelium 20 deposits or emits toxin 30 to reservoir 40. The stinger 10 opens a hole or wound opening in the top layer of the skin, the epidermis, of a recipient of about 1/2 to 2/3 of the length of the stinger and the toxin 30 enters the wound opening or hole via passage 50.

20           Figure 2 illustrates the average human epidermis 100 having a typical thickness ranging from 70 to 120 microns or an average thickness of 100 microns. The epidermis 100 has five distinct layers. The first layer 110 being the Stratum corneum. The second layer 120 being the Stratum lucidum. The third layer 130 being the Stratum granulosum. The fourth layer 140 being the Stratum spinosum. And the fifth layer 150 being the  
25   Stratum basale.

            Physicians treating dermatological disorders have long used dermabrasion or "Skin Planing" to treat problems ranging from acne to burns, dead tissue removal, and even cosmetically to eliminate wrinkles. Simply put – sand paper, emery cloth, files, graters and even wire bristles are used to strip the upper portion of the skin or epidermis from the  
30   dermis in anticipation of a smooth, non-pathological re-epidermization of the area (hopefully no more acne or wrinkles).

The use of abrading the epidermis for delivery systems for treatments and medications of the current invention can be analogized to the hypodermic needle; however, as the name indicates, hypo (beneath) dermis (skin) causes a deep wound for delivery or retrieval purposes. With the current invention, the method describes, e.g. delivery of toxin  
5 antagonists to shallow level where the toxins were delivered by the *Solenopsis Invicta* in the original wound or incursion and the instant invention may be thought of as a micro hypo "epi" dermic delivery system or an endodermis delivery system.

Besides the arthropod, the invention is applicable for *Cnidarian* and other biological envenomations (a.k.a. *Coelenterates*) stings. The *Cnidarians* consist of hydras,  
10 men o'war, jellyfish, sea anemones, hydrodroids, corals, bryozoans and the like. Characteristic of *Cnidarians* are nematocysts. These are the stinging cells which are usually deployed for food acquisition and/or for defensive purposes. Since all Nematocyst-bearing *Cnidarians* have essentially the same stinging cells, the Nematocysts of prime concern are stinging and stinging/tangling and will be generally dealt with, rather  
15 than specifically what was done with the *Solenopsis Invicta*. Figures 3 and 4 illustrate an armed Nematocyst 200 and a Discharged Nematocyst 210 respectively.

Because the *Cnidarians* use similar diminutive stinger size as with the *Solenopsis Invicta*, the use of the instant invention is similarly effective for the same reasons. The abrasive Debridement characteristics of the delivery pad are illustrated in Figure 5 at 300  
20 having a solution 310 saturated in the pad. 300. In addition, with many of the *Cnidarians* the nematocysts are barbed and pull away with the victim. The abrasive Debridement characteristics of the delivery pad 300 facilitate removal of these otherwise anchored weapons. From side 320 to 330, the pad can go from very abrasive to less abrasive, or even abrasive to smooth from one side to another. The pad could also be multilayered with  
25 a absorbent material backing a porous abrasive material where the absorbent material would carry the solution and be delivered through the abrasive material during application of slight pressure. An alternative could also be a type of bladder alone or in combination with the abrasive and absorbent material where the abrasive side would abrade and the application of pressure would burst the bladder releasing the solution at the desired  
30 moment or saturating the absorbent side thereby have at least a three layer pad with the bladder between the abrasive side and the absorbent side of the pad. The delivery of multiple combination could take place with multiple bladders of different solutions being

stacked up with the abrasive material so that the mixing of different solution could take place at the desired time or in desired sequence with the bladders being of different sequencing for bursting for specific combinative application of a solution.

The instant invention was tested on a number of humans, approximately one hundred or more individuals, who had received stings of the type disclosed above. The recipient or victims took a similar pad as described above that was saturated with a solution of soap and sterile water and a 2% Papain Enzyme that was manufactured in a foil type package similar to a towelette. Unlike the towelette, which is durable and soft, the instant pad is somewhat stiff and has an abrasive texture sufficient to plane the skin and deliver the solution to the planed epidermis. The method of the instant invention was used with success by over ninety-five percent of the people with immediate resolution of suffering by the recipient. The instant invention was also successful on bites or stings of unidentified species and genus.

During the discovery and clinical testing period, variation on the original method and pad became evident. Since demabrasion pad is premier delivery system for antitoxin, materials as described above for these series of pests, the treatment for use against other marine and land pests as listed in Tables 1 and 2 below have been accomplished and should be treated successfully with instant invention because the delivery of a toxin is similar as the instances above and the delivery of the antitoxins would be expected to have the same result.

TABLE 1

CLASSIFICATION	COMMON NAME	DISTRIBUTION
<b><u>PORIFERA</u></b>		
Family Desmacidonidae	Red Moss Sponge	U.S. Cape Code to
Family Tendaniidae	Fire Sponge	S. Carolina West Indies
<b><u>COELENTERATA</u></b>		
Hydrozoans		
Family Milliporidae	Stinging and/or Fire Coral	Tropical Pacific and Indian Oceans, Red Sea, &

CLASSIFICATION	COMMON NAME	DISTRIBUTION
Family Plumulariidae	Stinging Seaweed	Caribbean Tropical Pacific & Indian Oceans, West Indies
Family Physaciidae	Atlantic Portuguese Man-o-War Indo-Pacific Portuguese Man-o-War	Atlantic Ocean & Mediterranean Sea Tropical Indian & Pacific Oceans
<b><u>SCYPHOZOA</u></b>		
*Family Chirodropidae <sup>1</sup>	Deadly Sea Wasp; Box Jelly	Australian Pacific Coast
Family Carabidae	Sea Wasp	Tropical Pacific, Atlantic & Indian Oceans
Family Chirodropidae	Sea Wasp	Tropical Pacific, Atlantic & Indian Oceans
Family Cyaneidae	Sea Bubber; Lion's Mane	Northern Atlantic & Pacific, Baltic Sea, Tropical & Temperate Pacific Ocean
<b><u>ANTHOZOA</u></b>		
	Sea Anemones & Coral	World-wide
Family Acroporidae	Elkhorn Coral	Caribbean Sea
Family Actiniidae	Sea Anemone	Eastern Atlantic, Mediterranean, Black Sea & Sea of Asia
Family Actinodendronidae	Hell's Fire Sea Anemone	Atlantic & Pacific Oceans
Family Aliciidae	Sea Anemone	Red Sea
Family Hormathiidae	Sea Anemone	Eastern Atlantic, Mediterranean Sea, Coastal Africa
<b><u>ANNELIDA</u></b>		
	Segmented Worms	World-wide
Family Anphinomidae	Bristle Worm	Gulf of Mexico, Tropical

<sup>1</sup> \*Efficacy here is theorized & not tested

CLASSIFICATION	COMMON NAME	DISTRIBUTION
		Pacific & Atlantic Oceans
<b><u>ENCHINODERMATA</u></b>	Starfish, Sea Cucumbers, Sea Urchins	World-wide
Class Holothuriidea	Sea Cucumber	All Temperate Bodies of Water
Family Toxopneustidae	Sea Urchin	Pacific & Indian Oceans
<b><u>ECTOPEOGTA</u></b>		
Family Acyonidiidae	Bryozoans	World-wide

TABLE 2

<u>ARTHROPODA</u>	Spiders and Insects	Global
Myrmecinae	Ants	World-wide
<u>Examples:</u> SolStingenopsis Pogonomyemex Paraponera  Diptera and Acarina Nematocera Ceratopogonidae Culicoides Acari Culex Trichoceridac Mycelophilidae Chaoborinae Calliphoridae Sinuliidae	Fire Ants And Other Ants  No-see-ums, punkies gnats, moose flies, midges, biting midges blood sucking gnats, mites, chigoe, jigger, chigger, fleas, blow flies, blue bottle, biting housefly, stable fly, buffalo gnats, black flies	World-wide    World-wide



Further, the medication that will be saturated into the abrading pad will be in the form a solution of a sufficient dilution to permit transmission from the abrading pad during abrading or treatment of a wound or the surface of the recipient's skin. The solution in the pad can be a simple sterile water with a mild soap, an antibacterial formulation, a  
5 combination of water and isopropyl alcohol, water and hydrogen peroxide, an iodine solution and similar solution for cleaning and disinfecting or preventing infection.

Alternatively, the abrasive material can be a paste or a gel of sufficient abrasive character to abrade the epidermis sufficient to deliver the solution. The solution can be part of the constituents of the gel or paste, or separable therefrom through the use of a pad  
10 of material that would carry the solution.

Additionally, it is anticipated that this method of delivery for antitoxins for pests can be used as a delivery system for other dermatological medications, chemicals and variations combination of other medications and solutions, such as a prescription drug for delivery just below the surface of the skin, or an over the counter analgesic or skin  
15 treatment.

Not only may one consider using the instant invention for demabrasion and debridement but the cleansing that occurs with a lightly abrasive pad accompanied with a detergent could lend itself to a variety of other application particularly used in conjunction with a combination of other ingredients. Transdermally dispensed medications such as  
20 scopolamine, atropine and nicotine preparations would have their efficacy enhanced by lightly abrading the medication site, as well as all other topical and transdermal prescription medications.

As noted the solution that saturates the pad can be a ratio of soap and water that provides sufficient detergence to clean the wound and pH desired lavage. Furthermore, the  
25 pads can be impregnated with various solutions composed of enzymes, hypo-allergenic soap solutions, antihistamines solutions, anesthetic solutions, antibacterial solutions, antifungal solutions, antibiotic solutions, and combinations of any of the above for the specific treatment desired.

The selection of a construction or materials are not limited to those disclosed  
30 because the disclosure is one of example and not limitation. The abrasive material can be made of natural fibers such as linen, flax, cotton or wool, or plastic, or metal, or paper or a combination of all or some of the materials. The pad itself alone or the use with the gel or

paste can be made of natural fibers such as line, flax, cotton or wool, or plastic, or metal, or paper or a combination of all or some of the materials being of varying degrees or abrasiveness or smoothness. Furthermore, the present invention can incorporate just an abrasive pad saturated with a solution, or it can be a pad with a varying degree of abrasiveness on one side very abrasive and on the other side less abrasive, with the varying of degrees from side to side going from very abrasive on one side to almost smooth on the other side. While the present invention has been described with respect to what is presently an preferred embodiment and apparatus practicing the instant invention, it is understood that the invention is not limited to the disclosed embodiments or examples. To the contrary, the present invention is intended to cover various modifications and equivalent arrangement and configurations and steps included within the spirit and scope of the appended claims. The scope o the following claims is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent arrangements and functions.

## I Claim:

1. A method for delivering an sub-epidermal treatment comprising:
  - a. preparing a medicating solution;
  - b. saturating a saturatable material with sufficient abrasive characteristics to abrade the epidermis; and
  - c. abrading said epidermis where a said abrasion enables sub-epidermal delivery of said medicating solution in said saturated material.
2. The invention of claim 1 where the medicating solution comprises soap and water.
3. The invention of claim 1 where the medicating solution contains an antitoxin.
4. The invention of claim 1 where said sub-epidermal treatment is for treating a wound.
5. The invention of claim 4 where the wound has been caused by a arthropod.
6. The invention of claim 5 where the arthropod is *Solenopsis Invicta*.
7. The invention of claim 4 where the wound was caused by a *Cnidarian*.
8. The invention of claim 7 where the Cnidarian is a larval of the thimble jellyfish.
9. The invention of Claim 1 where the medicating solution contains an antibiotic.
10. The invention of claim 4 where the wound was biologically induced.
11. The invention of Claim 1 where the medicating solution contains an antifungal treatment.

12. The invention of Claim 1 where the medicating solution contains an antiseptic.
13. The invention of Claim 1 where said solution is a pH titer.
14. The invention of Claim 1 where the treatment is directed towards an intended surgical site.
15. The invention of Claim 1 where the treatment is directed towards a lesion.
16. The invention of Claim 15 where the lesion is an ulcer.
17. The invention of Claim 1 where the saturatable material with sufficient abrasive characteristics to abrade the epidermis is a paste, where such paste has a sufficient grittiness to abrade the epidermis.
18. A method for treating a pest sting comprising:
  - a. preparing a medication in the form of a solution;
  - b. saturating a saturatable material with sufficient abrasive characteristics to abrade the epidermis; and
  - c. abrading said epidermis where a wound has occurred with said saturated material.
19. The invention of claim 18 where the medicating solution comprises soap and water.
20. The invention of claim 19 where the medicating solution contains an antitoxin.
21. The invention of Claim 21 where said sub-epidermal treatment is for treating a wound.
22. The invention of claim 21 where the wound has been caused by a arthropod.
23. The invention of claim 22 where the arthropod is *Solenopsis Invicta*.
24. The invention of claim 21 where the wound was caused by a *Cnidarian*.

25. The invention of claim 24 where the *Cnidarian* is a larval of the thimble jellyfish.
26. The invention of Claim 18 where the medicating solution contains an antibiotic.
27. The invention of Claim 18 where the medicating solution contains an antifungal treatment.
28. The invention of Claim 18 where said solution is a pH titer.
29. The invention of Claim 18 where the treatment is directed towards an intended surgical site.
30. The invention of Claim 18 where the treatment is directed towards a lesion.
31. The invention of Claim 30 where the lesion is an ulcer.
32. The invention of Claim 18 where the saturatable material with sufficient abrasive characteristics to abrade the epidermis is a paste, where such paste has a sufficient grittiness to abrade the epidermis.
33. A method for delivering an inter-epidermal treatment comprising:
  - a. preparing a medicating solution;
  - b. saturating a saturatable material with sufficient abrasive characteristics to abrade the epidermis; and
  - c. abrading said epidermis where a said abrasion enables sub-epidermal delivery of said medicating solution in said saturated material.
34. The invention of claim 33 where the medicating solution comprises soap and water.
35. The invention of claim 34 where the medicating solution contains an antitoxin.

36. The invention of Claim 35 where said sub-epidermal treatment is for treating a wound.
37. The invention of claim 36 where the wound has been caused by a arthropod.
38. The invention of claim 37 where the arthropod is *Solenopsis Invicta*.
39. The invention of claim 36 where the wound was caused by a *Cnidarian*.
40. The invention of claim 39 where the *Cnidarian* is a larval of the thimble jellyfish.
41. The invention of Claim 33 where the medicating solution contains an antibiotic.
42. The invention of Claim 33 where the medicating solution contains an antifungal treatment.
43. The invention of Claim 33 where said solution is a pH titer.
44. The invention of Claim 33 where the treatment is directed towards an intended surgical site.
45. The invention of Claim 33 where the treatment is directed towards a lesion.
46. The invention of Claim 45 where the lesion is an ulcer.
47. The invention of Claim 33 where the saturatable material with sufficient abrasive characteristics to abrade the epidermis is a paste, where such paste has a sufficient grittiness to abrade the epidermis.
48. A method for improved transdermal delivery a medicating solution comprising:
- a. preparing a medicating solution;
  - b. saturating a saturatable material with sufficient abrasive characteristics to abrade the epidermis; and

- c. prior to application of transdermal delivery system, abrading said epidermis where said transdermal system will contact the surface of the component of a recipient.

49. The invention of claim 48 where the medicating solution of a sufficient dilution to permit transmission from the abrading pad during abrading or treatment of a wound or the surface of the recipient's skin.

50. The invention of claim 48 where the medicating solution of a sufficient dilution to permit transmission from the abrading pad during abrading or treatment of a wound or the surface of the recipient's skin.

51. The invention of claim 48 where the medicating solution of a sufficient dilution to permit transmission from the abrading pad during abrading or treatment of a wound or the surface of the recipient's skin.

52. The invention of claim 48 where the medicating solution of a sufficient dilution to permit transmission from the abrading pad during abrading or treatment of a wound or the surface of the recipient's skin.

53. The product for practicing the method of Claim 1 comprising:

- a. an abrasive material;
- b. said abrasive material capable of abrading at least part of the epidermis; and
- c. said abrasive material capable of being saturated with a medicating solution.

54. The product for practicing the method of Claim 18 comprising:

- a. an abrasive material;
- b. said abrasive material capable of abrading at least part of the epidermis; and
- c. said abrasive material capable of being saturated with a medicating solution.

55. The product for practicing the method of Claim 33 comprising:

- a. an abrasive material;
- b. said abrasive material capable of abrading at least part of the epidermis; and

- c. said abrasive material capable of being saturated with a medicating solution.
56. The product for practicing the method of Claim 18 comprising:
- a. an abrasive material;
  - b. said abrasive material capable of abrading at least part of the epidermis; and
  - c. said abrasive material capable of being saturated with a medicating solution.
57. A method for delivering an sub-epidermal treatment comprising:
- a. preparing a medicating solution;
  - b. saturating a saturatable material with sufficient abrasive characteristics to abrade the epidermis, where the saturatable material with sufficient abrasive characteristics to abrade the epidermis is a paste; and
  - c. abrading said epidermis where a said abrasion enables sub-epidermal delivery of said medicating solution in said saturated material.
58. The invention of Claim 57 where material with sufficient abrasive characteristics to abrade the epidermis is a gel with sufficient abrasive characteristics to abrade the epidermis.



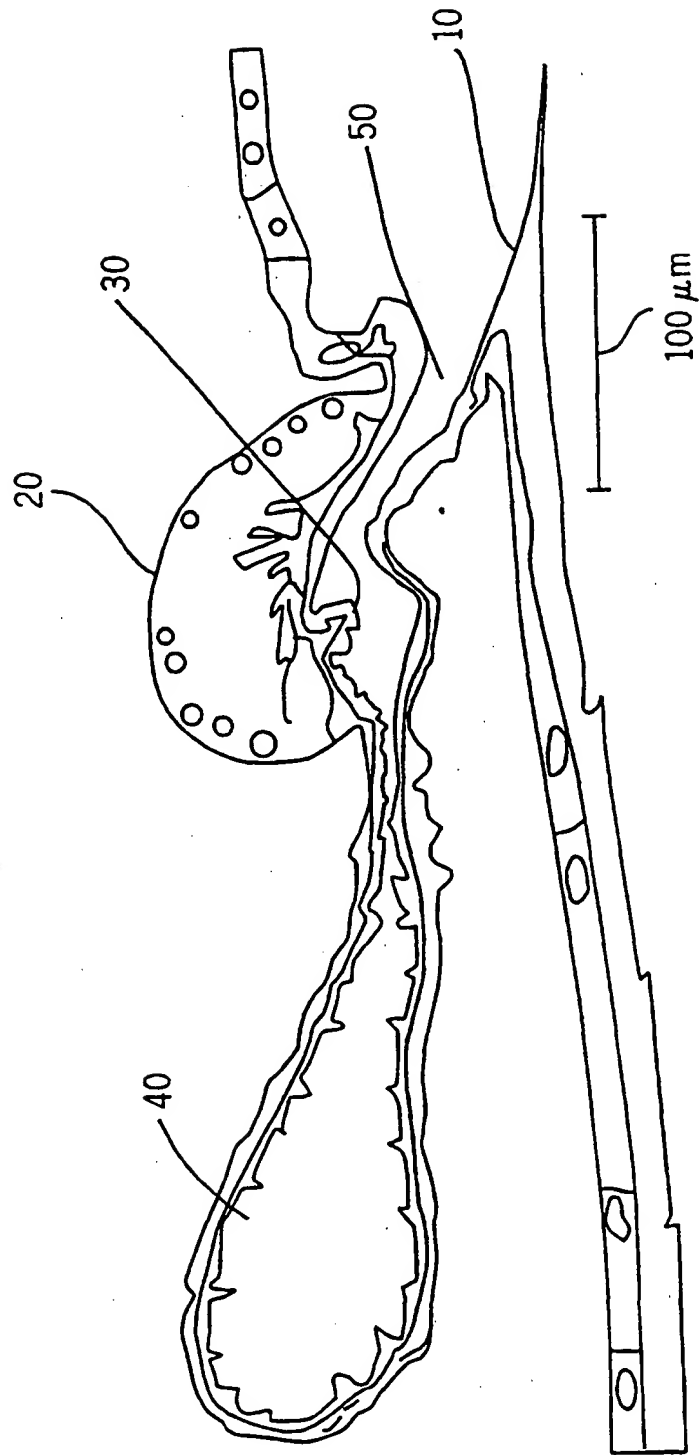
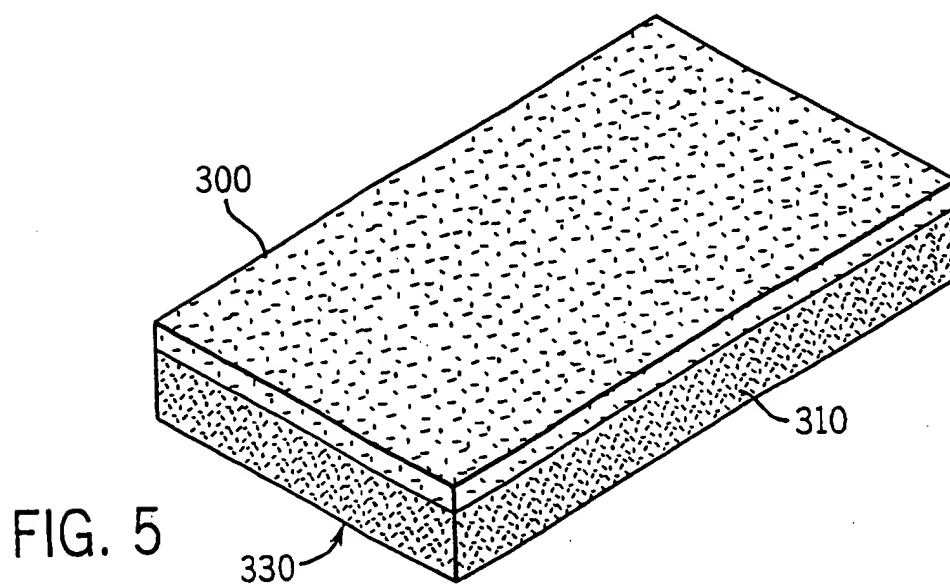
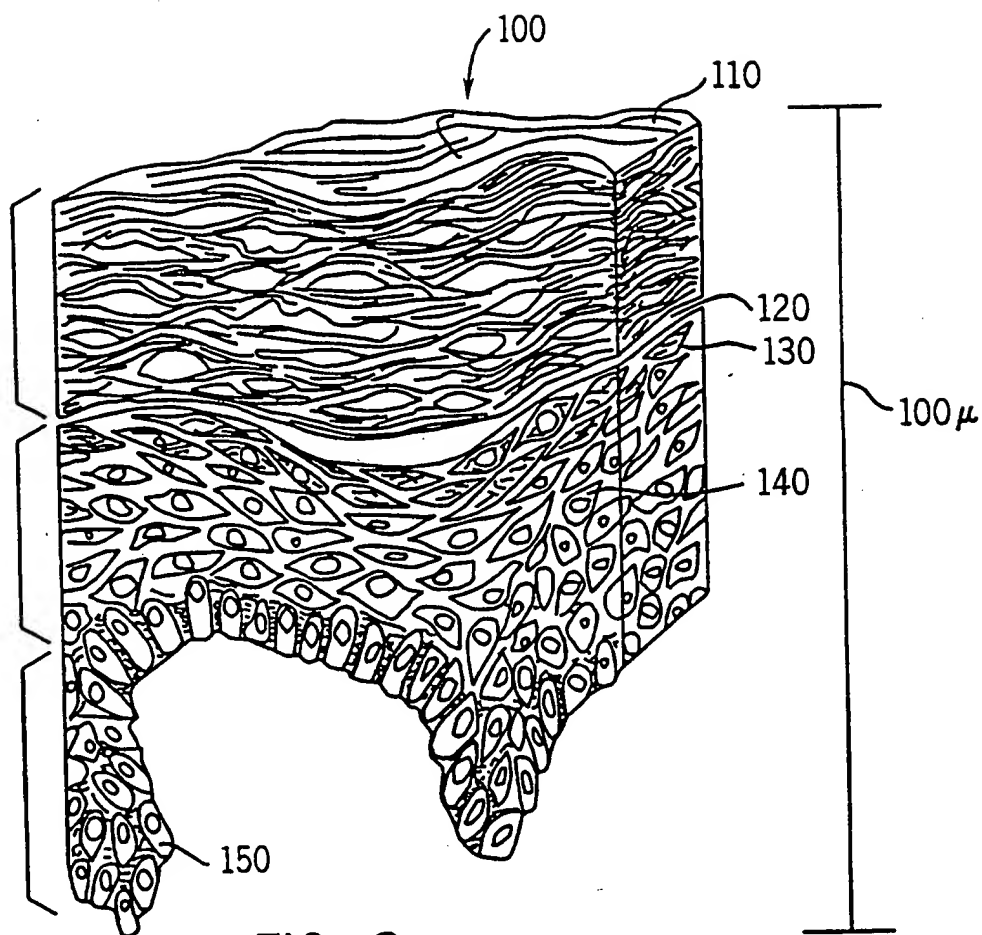


FIG. 1



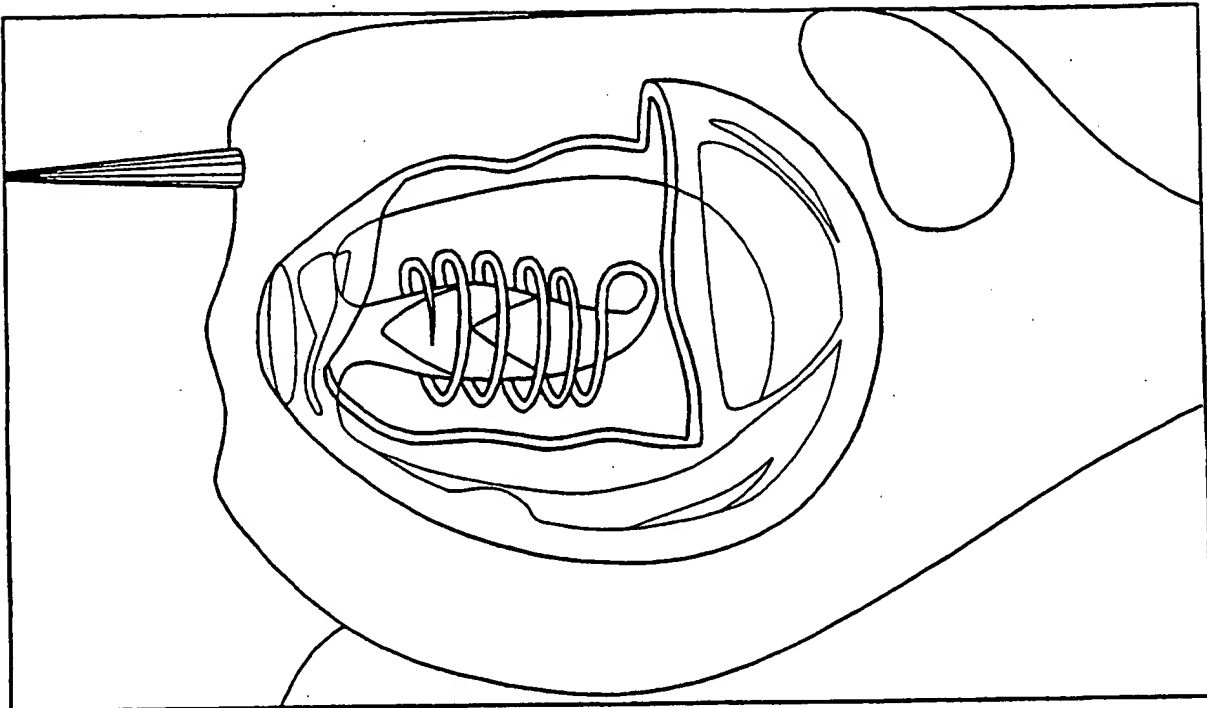


FIG. 3

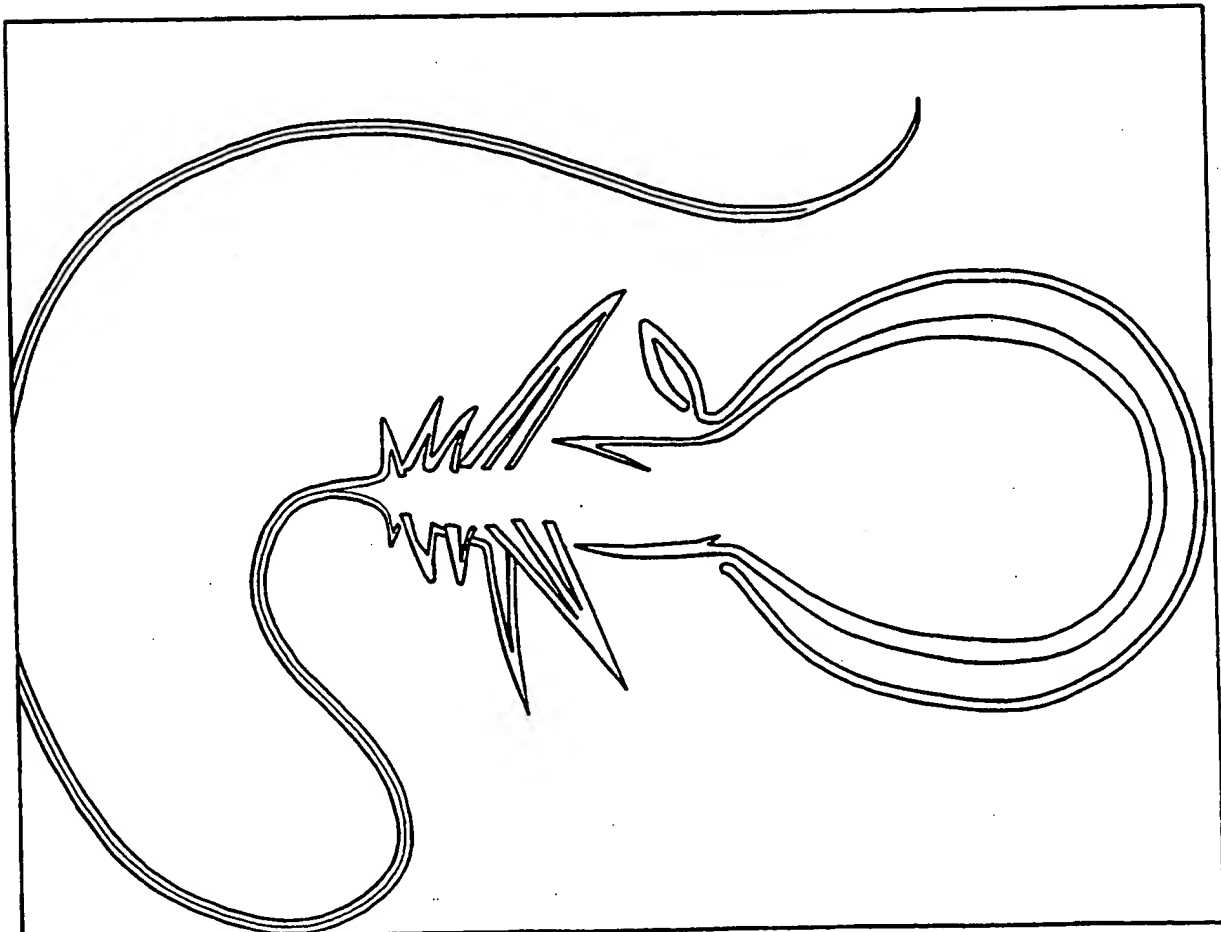


FIG. 4

## INTERNATIONAL SEARCH REPORT

Intern. Application No

PCT/US 99/31040

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M35/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 778 457 A (YORK ) 18 October 1988 (1988-10-18) the whole document	53-56
X	US 4 696 393 A (LAIPPLY ) 29 September 1987 (1987-09-29) abstract column 1, line 15 - line 23 column 7, line 4 - line 10; figures 1-3	53-56
A	WO 85 04794 A (WHITMAN MED. CORP-.) 7 November 1985 (1985-11-07)	

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

10 April 2000

Date of mailing of the international search report

17/04/2000

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 31040

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-52, 57, 58  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body  
by therapy
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such  
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all  
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment  
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report  
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is  
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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